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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,318	10/24/2003	John S. Patton	0001.13	8226

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EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	PAPER NUMBER
3771	

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12/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,318	PATTON ET AL.	
	Examiner	Art Unit	
	Kristen C. Matter	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/20/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the Request for Continued Examination filed on 10/31/2007. Claims 2, 5, 7, 11, 14, and 16 have been amended and claims 26-39 have been added. Currently, claims 2-39 are pending in the application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 5-7, 9-11, 14-26, 18-20, 23, 26, 27, 30, 31, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calvert et al. (US 5,522,383) in view of Saifer et al. (US 4,022,224).

As to claims 2, 11, 26, and 27, Calvert et al. discloses an apparatus for producing aerosolized medicament, the apparatus comprising: a reservoir (capsule 5a, 5b) containing powder medicament to be aerosolized; and a chamber (25) comprising first and second air inlets (26) and a mouthpiece (27), wherein gas may flow into the chamber through the inlet and may flow out of the chamber through the mouthpiece and wherein the flow of gas aerosolizes the powder medicament. Furthermore, Calvert et al. discloses that the gas is introduced to the chamber at a swirl angle to create a vertical flow (col. 4, lines 35-40). To the extent that Calvert et al. does not explicitly disclose that at least 40% by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece, examiner contends

that Calvert et al. does explicitly disclose that the device delivers as much of the medicament as possible (col.4, lines 35-55). Depending on the specific characteristics of the powder, the exact percent of medicament delivered would vary to a certain degree, but the structure of Calvert et al. would not prevent at least 40% by weight of the medicament to be suspended and delivered, thereby reading on the instant claim. In addition, to the extent that Calvert et al. is silent as to the volume of medicament aerosolized, absent a critical teaching and/or a showing of unexpected results from the volume of aerosolized medicament being 9.24-21.5% of the volume of the chamber, examiner contends it is an obvious design consideration to one of ordinary skill in the art to aerosolize a large range of medicament volumes, including 9.24-21.5% of the chamber volume, depending on the amount of medicament needed to treat the patient for a given condition and who is using the device (i.e., pediatric, adult). Again, examiner argues that the structure of Calvert et al. does not prevent one of ordinary skill in the art from sizing the chamber such that the volume of aerosolized medicament is 9.24-21.5% of the volume of the chamber, and it appears as though the device of Calvert et al. would perform equally well with the claimed dimensions. The difference between Calvert et al. and claim 2 is the powder medicament comprising a protein or polypeptide. Saifer et al. teach a protein (e.g. orgotein) in the form of a powder medicament for administration to a patient suffering from smoke inhalation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the powdered medicament of Calvert et al. with a protein such as orgotein as taught by Saifer et al. because it would have provided a means for treating patients suffering from smoke inhalation using the device disclosed by Calvert et al.

As to claims 5, 14, and 30, the chamber disclosed by Calvert et al. is adapted to contain aerosolized medicament for subsequent delivery to a patient (abstract).

As to claims 6 and 15, the chamber (25) of Calvert et al. is cylindrical (Figure 8).

As to claims 7, 16, and 31, although Calvert et al. is silent as to the particle size, it would have been an obvious design consideration to one of ordinary skill in the art to use particles being sized to be deliverable to the alveolar regions of the lungs in order to treat various conditions of the patient by enabling deeper penetration into the respiratory tract of a patient.

As to claims 9, 10, 18, 19, and 33, Calvert et al. as discussed above with respect to claim 2, discloses a need for as high as possible degree of emptying of the reservoir (5a, 5b) and chamber for properly treating a patient (column 4, lines 45-55). Therefore, at least 55% and at least 70% by weight of the powdered medicament being suspended by the gas in the chamber for delivery through the mouthpiece is an obvious design consideration to one of ordinary skill in the art for delivery of as close to a full dose as possible. Furthermore, as discussed above, the structure of Calvert et al. does not prevent this amount of medicament from being aerosolized.

As to claims 20, 23, and 34, Calvert et al. discloses at least one air inlet oriented tangentially in the chamber (Figure 7).

Claims 3, 12, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calvert et al. in view of Saifer et al. as applied to claims 2, 5-7, 9-11, 14-26, 18-20, 23, 26, 27, 30, 31, 33, and 34 above, and further in view of Moren et al. ('712). While Calvert et al. is silent as to the dimensions of the chamber, the chamber size can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular chamber size

including 100ml to 750ml. The treatment of adult patients vs. children would require a larger chamber due to increased tidal volume and lung capacity of adults. Otherwise, resort is had to Moren, which teaches an expansion chamber having a volume in the range of 500ml to 2000ml (see figure) for reducing propellant and generating smaller medicament particles which will more readily follow the path of inhalation (see abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the chamber of Calvert et al. to have a volume in the claimed range because it would have provided a means for reducing propellant and generating smaller medicament particles which will more readily follow the path of inhalation as taught by Moren. In addition, it appears as though the device disclosed by Calvert et al. would perform equally well with the claimed dimensions.

Claims 4, 8, 13, 17, 29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calvert et al. in view of Saifer et al. as applied to claims 2, 5-7, 9-11, 14-26, 18-20, 23, 26, 27, 30, 31, 33, and 34 above, and further in view of Hansen (US 3,809,084).

As to claims 4, 13, and 29 Calvert et al. does not disclose a source of compressed gas for aerosolizing the medicament. However, Hansen, in a powdered medicament inhaler, discloses the use of a source of compressed gas (14) for aerosolizing powder medicament in a reservoir. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the inhaler of Calvert et al. to include use of a source of compressed gas as taught by Hansen in order to allow the medicament to be delivered for local therapy (i.e., vagina, ear, wound) or to supplement individuals with a weakened respiratory system (i.e., asthma

patients or children that might not be able to inhale strongly enough to properly aerosolize the powder).

As to claims 8, 17, and 32, Calvert et al. is silent as to the particle diameters. Hansen discloses particle size range to predominate (90%) below 5 microns (column 3, lines 45-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used particles sizes that are predominately 1-5 microns as taught by Hansen in the modified Calvert et al. device for delivering the medicament to targeted regions of the lungs.

Claims 21, 24, 35-37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calvert et al. in view of Saifer et al. as applied to claims 2, 5-7, 9-11, 14-26, 18-20, 23, 26, 27, 30, 31, 33, and 34 above, and further in view of Abplanalp (US 4,396,152).

As to claims 21, 24, and 35, Calvert et al. does not disclose one air inlet not being oriented tangentially in the chamber. However, Abplanalp discloses an aerosolizing device in which one air inlet is not oriented tangentially and a second inlet is not oriented tangentially to create a vortical flow for aerosolizing particles (column 3, lines 38-45). It would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have oriented one inlet non-tangentially and one inlet tangentially to the chamber as taught by Abplanalp in the modified Calvert et al. device for producing the vortical flow. In addition, it appears as though the device disclosed by Calvert et al. would perform equally well with the air inlets oriented in this fashion.

As to claims 36, 37, and 39, please see above rejections with respect to claims 2, 3, 5, 11, 12, and 14.

Claims 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calvert et al. in view of Saifer et al. as applied to claims 2, 5-7, 9-11, 14-26, 18-20, 23, 26, 27, 30, 31, 33, and 34 above, and further in view of Kirk et al. (US 4,860,740). Calvert et al. does not disclose the mouthpiece being oriented tangentially in the chamber. However, Kirk et al., in a powder inhalation device, disclose a mouthpiece oriented tangentially to a chamber containing aerosolized medicament (Figure 1). Therefore, it would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have oriented the mouthpiece of the modified Calvert et al. device tangentially to the chamber as taught by Kirk et al. for helping produce the vortical flow or for easier exit of the aerosolized medicament from the chamber. In addition, it appears as though the device disclosed by Calvert et al. would perform equally well with the mouthpiece oriented in this fashion.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Calvert et al. in view of Saifer et al. and Abplanalp as applied to claims 21, 24, 35-37, and 39 above, and further in view of Hansen. Calvert et al. as modified by Saifer et al. and Abplanalp does not disclose a source of compressed gas for aerosolizing the medicament. However, Hansen, in a powdered medicament inhaler, discloses the use of a source of compressed gas (14) for aerosolizing powder medicament in a reservoir. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the inhaler of Calvert et al. to include use of a source of compressed gas as taught by Hansen in order to allow the medicament to be delivered for local therapy (i.e., vagina, ear, wound) or to supplement individuals with a

weakened respiratory system (i.e., asthma patients or children that might not be able to inhale strongly enough to properly aerosolize the powder).

Response to Arguments

Applicant's arguments filed 10/31/2007 have been fully considered but they are not persuasive.

In response to applicant's argument that Calvert et al. does not discuss the percentage amount of suspension (regarding a percent weight as in claim 2 or the volume of the chamber as in claim 11), examiner acknowledges that specific values of suspension amounts are not disclosed, but rather that it is desirable to suspend as much medicament as possible for inhalation. The structure of Calvert et al. would in no way prohibit one of ordinary skill in the art from modifying Calvert et al. to suspend the claimed amount of medicament or to size the chamber as claimed. Depending on the medicament to be delivered for a given treatment and the patient (i.e., adult, pediatric) various amounts of medicament could be dispersed by the Calvert et al. device, including at least 40, 55, or 70 percent weight of the powder or 9.24-21.5% of the volume of the chamber.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art could be expected to combine the references because Saifer et al. discloses that the protein is delivered by inhalation in an aerosol as a powder (column 2, lines 35-40) and Calvert et al. disclose a device for administering powder medicament for inhalation. Saifer et al. is cited merely to show that it was known at the time of the invention that proteins could be delivered by inhalation therapy. Therefore, to treat the toxic effects of smoke, for example, as taught by Saifer et al., one of ordinary skill in the art could be expected to turn to Calvert et al. for an efficient means of aerosolizing the orgotein for inhalation. Furthermore, there is no indication in either reference that the proposed modification would not be successful.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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12/12/07